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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,226	10/09/2001	Sanjeev Kothari	CT2545ACIP	7273

23914 7590 11/05/2003

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EXAMINER	
PULLIAM, AMY E	

ART UNIT	PAPER NUMBER
1615	10

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/973,226	Applicant(s) KOTHARI ET AL.	
	Examiner Amy E Pulliam	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4 and 7-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,4 and 7-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Amendment A, received by the Office August 19, 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 20-27, 30, 32, 33, 35, and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites, "wherein said dispersing agent comprises from about 20 to about 70 percent by weight of said dispersing agent." This language is very confusing. How can a dispersing agent be made of a percent of dispersing agent? Isn't the dispersing agent completely made of dispersing agent? Does Applicant mean the formulation as a whole comprises from about 20 to about 70 percent of a dispersing agent? If so, the claim should be amended to reflect this.

Claims 3, 20-27, 30, 32, 33, 35, and 36 are phrase similarly to claim 2 and should be corrected or clarified in the same manner.

Response to Arguments

Applicant's arguments regarding the 112, second paragraph rejection have been considered but are not found to be persuasive. Applicants traverse the rejection on the grounds

that claim 3 incorporated language which satisfies the examiner's concern. (This language is now present in claim 2). Applicant believes that this language reflects the clarity sought by the Examiner. The Examiner respectfully disagrees. Claim 2 now recites the language "wherein said dispersing agent comprises from about 20 to about 70 percent by weight of said dispersing agent based on the total weight of said dosage form." This language is still found to be confusing by the examiner. How can a dispersing agent by 20 – 70% of said dispersing agent? Again, the Examiner reiterates her previous questions. Is there another disintegrant present to make up the other 80-30% of the disintegrant? Or, does Applicant meant that the disintegrant as a whole is present as 20-70% of the entire formulation? This language has not been clarified by the present amendments, and therefore this rejection under 35 USC 112, second paragraph is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2,4,and 7-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/03064 to Sullivan.

Sullivan discloses a composition useful as an excipient for increasing the disintegration rate of solid dosage forms of active agents in pharmaceutical and other formulations. Sullivan teaches that the composition of the invention may readily be prepared by combining the super

disintegrants with the co-disintegrants in any suitable manner known in the art (p 3, l 20-22). Sullivan teaches that the superdisintegrant may be chosen from croscarmellose sodium, crospovidone, and sodium starch glycolate (p 4, l 25-28). The co-disintegrant may be a silica, such as calcium silicate (p 5, l 4-14). Additionally, the co-disintegrant can be present in the composition from about 0.05 to about 10 % by weight, and can additionally replace between 20 and 90% of the superdisintegrant (p 23, claims 12 and 13). Additionally, the active agent comprises from about 10 to about 95% of the total dosage form (p 23, claim 17). The composition may further include additives and adjuvants, such as lubricants, binders, dispersants, and fillers (p 6, l 20-27). Sullivan teaches magnesium aluminum silicate as a disintegrant and microcrystalline cellulose as a binder (p 7, l 10-20).

Sullivan is described above as teaching a composition useful as an excipient for increasing the disintegration rate of solid dosage forms of active ingredients.

Sullivan does not teach the specific active agents claimed by Applicant. It is the position of the examiner that absent a showing of unexpected results, the use of a known active agent in a pharmaceutical composition is not patentable. Sullivan teaches a generic concept, by making a composition for use with a vast number of active agents, wherein the disintegration rate is increased. It would have been obvious to one of ordinary skill in the art to use any active agent in the composition taught by Sullivan where it would be beneficial to increase the disintegration rate. If the particular actives claimed by Applicant provide unexpected results in this type of formulation, it is suggested that these result be submitted in Declaration form. Otherwise, the mere substitution of one well known active agent for another active agent in a generic teaching of a dosage form is not patentable.

Additionally, Sullivan does not specifically teach that the calcium silicate is either amorphous or crystalline. This, however, is not found to render patentable distinction to the claims, because the reference teaches calcium silicate in general, and this general form suggests both the crystalline and the amorphous form of the component. Furthermore, Sullivan does not teach that the calcium silicate be the alpha triclinic form, nor does the reference teach the particular surface areas or densities of the additive. It is the position of the examiner that absent a showing to the contrary, the calcium silicate disclosed by Sullivan possesses the same characteristics as the one claimed by Applicant. Both Applicant and Sullivan's compositions fulfill the same purpose or fast disintegration, and both use the same components to reach the same result. Therefore, it is the position of the examiner that claiming the particular properties of a known and used compound does not make the instant claims patentable over the prior art.

It is the position of the examiner that the teachings of Sullivan suggest the limitations of Applicant's pending claims. Sullivan teaches a composition for use in increasing the rate of disintegration of a pharmaceutical composition, and Sullivan teaches the use of the same components in said composition. It is within the skill of the ordinary worker to use any well known active agent in a generic pharmaceutical composition, with the expected result in this instance being a successful and rapidly disintegrating dosage form. The motivation lies in the generic teachings of Sullivan, which describe the dosage form for use in many different areas with many different active agents. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed August 19, 2003 have been fully considered but they are not persuasive.

Applicant first argues that Sullivan is non-analogous art because it teaches immediate release rather than a flash melt dosage form. The Examiner respectfully disagrees. It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

Applicant also argues that Sullivan is primarily focused on substituting costly superdisintegrants with less expensive co-disintegrants. This argument is not persuasive. If Sullivan teaches or suggests the limitations of the claimed compositions, then the purpose behind the reference does not negate this teaching.

Applicant further argues that although the cited reference exemplifies 25% active agent, it teaches that the active can be present at between 10 and 95% of the composition. Applicant contends that their active can not be present at more than 30%. This argument is not persuasive. Although Sullivan allows a large range of percentages with regard to the amount of active agent, he does teach that ideally 25% of active is present. The fact that the ranges overlap is enough to suggest the limitations of Applicant's claimed range.

Applicant also argues that Sullivan teaches 0.01 to 9.0% calcium silicate, while Applicant teaches 20-70%. The examiner restates a portion of the rejection found above. The co-

disintegrants may be a silica, such as calcium silicate (p 5, l 4-14). Additionally, the co-disintegrant can be present in the composition from about 0.05 to about 10% by weight, and can additionally replace between 20 and 90% of the superdisintegrants (p 23, claims 12 and 13). Therefore, the amount of calcium silicate included in Sullivan's formulation is actually much larger than 0.05 to 10% if portions of the superdisintegrant are replaced. Therefore, this argument is not found to be persuasive.

Lastly, Applicant argues that Sullivan teaches 0.05-8% superdisintegrants, with 0.045-2.4% preferred, while Applicant teaches 4-8% with 5-7% preferred. For the same reason discussed above, this argument is not found to be pervasive. Sullivan clearly teaches a range which overlaps the range claimed by Applicant, and therefore clearly suggests the claimed limitation.

For the above reasons, the above rejections are maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
Art Unit 1615
October 31, 2003

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